In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 21-0443V

MEAGAN POWERS, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: September 4, 2024

John Robert Howie, Howie Law, PC, Dallas, TX, for Petitioner.

Matthew Murphy, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

On January 11, 2021, Meagan Powers filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"), alleging that she suffered a shoulder injury related to vaccine administration ("SIRVA") as a result of an influenza ("flu") vaccine which she received on September 22, 2020. The case was assigned to the Special Processing Unit of the Office of Special Masters (the "SPU").

[1] Because this ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

For the following reasons, I find that under the Act's "more likely than not" standard of proof, Petitioner has established that her post-vaccination shoulder injury and its residual effects persisted for over six months, and that her shoulder pain began within forty-eight (48) hours. And based on the lack of any other objections from Respondent, along with an independent review of the record, I find that Petitioner has preponderantly established all other requirements for a Table SIRVA claim – meaning that she is entitled to compensation. However, the record also reflects a very mild injury, and the parties are urged to agree on an appropriate compensation award rather than further litigating the case.

I. Procedural History

Petitioner filed her claim less than six months post-vaccination, and without supporting medical records – coinciding with Respondent's proposal to remove SIRVA from the Vaccine Injury Table that would govern future petitions.[3] But that same year she amended the Petition, establishing severity, and also offered a declaration[4] and medical records (ECF Nos. 10 – 11). In January 2022, the case was deemed to be sufficiently complete, and assigned to the SPU (OSM's scheme for managing claims that have traditionally resolved informally or without extensive litigation). In July 2022, Petitioner was instructed to promptly prepare a demand for Respondent's consideration while awaiting completion of Respondent's medical review. Scheduling Order (ECF No. 25). Instead on February 28, 2023, Petitioner filed a Motion for a Ruling on the Record regarding her entitlement to compensation for a Table SIRVA (hereinafter "Brief") (ECF No. 29).[5, 6]

[3] On July 20, 2020, the Secretary of Health and Human Services proposed the removal of SIRVA from the Vaccine Injury Table. *National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Proposed Rule*, 85 Fed. Reg. 43794 (July 20, 2020). The proposed rule was finalized six months later. *National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Final Rule*, 86 Fed. Reg. 6249 (Jan. 21, 2021). Approximately one month later, the effective date for the final rule was delayed. *National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Delay of Effective Date*, 86 Fed. Reg. 10835 (Feb. 23, 2021) (delaying the effective date of the final rule until April 23, 2021). On April 22, 2021, the final rule removing SIRVA from the Vaccine Table was rescinded. *National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Withdrawal of Final Rule*, 86 Fed. Reg. 21209 (Apr. 22, 2021).

[4] Petitioner's declaration is sworn under penalty of perjury. Ex. 1 at 2; *see also* 28 U.S.C.A. § 1746 (providing that such a declaration may be afforded like force and effect as a notarized affidavit).

[5] Petitioner's Brief also set forth her position regarding the appropriate award of damages for a Table SIRVA claim and was accompanied by Ex. 15 – Out of Pocket Expense Documentation (ECF No. 28).

[6] Petitioner also filed a second Amended Petition – but the only amendment seems to be the addition of an alternative claim of causation-in-fact, in the preamble/ introductory paragraph. *Compare* First Amended Petition (ECF No. 9), with Second Amended Petition filed Feb. 28, 2023 (ECF No. 30).

Respondent reported his opposition to the claim on March 7, 2023 (ECF No. 31) and filed his Rule 4(c) Report on May 2, 2023 (ECF No. 32). The parties made additional filings. Ex. 16 (ECF No. 34) and Petitioner's ("Pet.") Response (ECF No. 35) both filed June 15, 2023; Respondent's ("Resp.") Reply filed July 17, 2023 (ECF No. 36): Pet. Reply filed July 18, 2023 (ECF No. 37). The matter is now ripe for adjudication.

II. Authority

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding his claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs.,* 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. *See Cucuras v. Sec'y of Health & Hum. Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records testimony, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." *Sanchez v. Sec'y of Health & Hum. Servs.,* No. 11–685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec'y of Health & Hum. Servs.,* No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,[7] a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the

[7] In summary, a petitioner must establish that he received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of his injury for more than six months, died from his injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. *See* Section 11(c)(1)(A)(B)(D)(E).

time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of a flu vaccine. 42 C.F. R. § 100.3(a)(XIV)(B). The criteria establishing a SIRVA under the accompanying QAI are as follows:

> Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g., tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time frame;
>
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
>
> (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g., NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10) (2017).

III. Evidence

I have reviewed all submitted evidence, including all medical records and affidavits, as well as the Petition, the Rule 4(c) Report, and both parties' briefing. The following section focuses on the facts most relevant to the disputed issues (severity and onset).

On September 22, 2020, Petitioner received the at-issue flu vaccine in her left deltoid muscle during an annual gynecological exam with Ann E. Lutich, M.D. Ex. 2 at 1; Ex. 3 at 2, 51 – 56. She was forty-one (41) years old, with no pertinent medical history. *See generally* Exs. 3, 7.

Thirteen (13) days later, on October 5, 2020, Petitioner texted "Ann,"[8] asking whether it was common to have injection site soreness/ pain that was still present after the flu shot, despite conservative treatment (ice packs, massage, Aleve). Ex. 9 at 1. The pain was currently "slightly worse than it was the day after the shot." *Id.* "Ann" responded that she had seen "this happen after injections, and it can take several weeks but should resolve." *Id.*

On October 8, 2020, Petitioner texted "David,"[9] who responded that it would be appropriate to have her shoulder evaluated. Ex. 10 at 1.

On October 12, 2020, at Texas Orthopedic Associates, Petitioner filled out new patient paperwork, including a chief complaint of left shoulder pain that was "constant" since receiving her flu shot on 9/22/2020. Ex. 4 at 107. That same day, during the initial evaluation, Robert Scheinberg, M.D., recorded a similar history ("flu vaccine… the pain in the left shoulder has continued for almost three weeks now"), and exam findings of injection site tenderness, pain with forward flexion and crossed arm to abduction, and mild weakness with resisted external rotation and forward flexion. *Id.* at 118. Dr. Scheinberg's assessment was impingement syndrome, while also referencing the potential of "SIRVA reaction to the flu shot." *Id.* at 118. He planned a Medrol dose pack, formal physical therapy ("PT") and following up in 2 – 3 weeks. *Id.*

At an October 21, 2020, follow-up, Dr. Scheinberg recorded that Petitioner's left shoulder pain had significantly decreased with the Medrol dose pack, then started to come back "a little." Ex. 4 at 115. On exam, the shoulder seemed to be moving much

[8] The text messages' content, the medical records, and Petitioner's statement (Ex. 1 at ¶ 6) preponderantly support that "Ann" in the text messages was the treating gynecologist Dr. Lutich.

[9] Similarly, the text messages' content, the medical records, and Petitioner's statement (Ex. 1 at ¶ 6) preponderantly support that "David" was David Heck, a physician's assistant working under Dr. Scheinberg's supervision. *See, e.g.*, Ex. 4 at 119.

better; Petitioner was less hesitant and perhaps a bit stronger. *Id.* Dr. Scheinberg's plan was to "remain conservative," with a focus on PT to build further strength and range of motion ("ROM"). *Id.* They also decided against a steroid injection at that time, while considering that it "might be needed down the road." *Id.*

At the October 22, 2020 PT initial evaluation, Petitioner again reported left shoulder pain and reduced ROM following a flu shot. Ex. 11 at 2. The pain was currently "burning" and rated 2 – 4/10; she was not taking any medications. *Id.* Her upper extremity DASH score was 25/100. *Id.* at 2, 5. An exam found decreased ROM and tenderness to palpation. *Id.* at 2 – 3.[10] The assessment was "SIRVA," for which the therapist recommended formal PT and a home exercise program ("HEP"), with a focus on improving her ROM and strength. *Id.* at 3 – 4. Petitioner returned for formal PT on October 27, and November 2, 2020. *Id.* at 6 – 7.

At a November 6, 2020 follow-up with Dr. Scheinberg, Petitioner reported that she had done well with her Medrol dose pack before starting PT. Ex. 4 at 113. Her shoulder was a little bit better but still uncomfortable; she was also having a hard time reaching and lifting, and still felt weak. *Id.* On exam, the shoulder had "full" ROM, but "her mechanics [were] off[,] she hike[d] her scapula with abduction and forward flexion[, and] she ha[d] slight weakness to resisted external rotation secondary to pain [and…] mildly positive Speed's test." *Id.* Dr. Scheinberg administered a subacromial corticosteroid injection, and recommended continuing PT for six weeks before returning for his reevaluation. *Id.*

At two additional PT sessions on November 10 and November 19, 2020, Petitioner reported that since the steroid injection, her shoulder movement and pain had improved. She received phonophoresis and manual therapies, plus additional instruction on her HEP. However, these records do not include physical examination findings, or indicate any updates to her problems or goals. Ex. 11 at 8 – 9.

There is a subsequent gap in any documentation of Petitioner's left shoulder – or any medical encounters for any other reason. That is followed by a June 15, 2021 PT "recertification" note, which states that Petitioner was "return[ing] with mild weakness, instability, popping but overall symptoms are better." Ex. 12 at 3. The physical examination findings were essentially identical to those from the October 22, 2020 PT initial evaluation. *Compare* Ex. 12 at 3 – 4 with Ex. 11 at 2 – 3. Similarly, all of Petitioner's answers on a "Patient Outcomes" questionnaire were identical. *Compare* Ex. 12 at 6 with

[10] The PT records indicate that the abnormal exam findings were in the opposing *right* shoulder – but this is more likely than not an error, given that it would be inconsistent with the otherwise consistent notations, in the PT records and others, that Petitioner had suffered only a *left* shoulder injury.

Ex. 11 at 5. But the therapist recorded a different upper extremity DASH score of 16/100 (improved from 25/100), and newly assessed: "mild loss of strength, stability, and will benefit from skilled interventions to restore normal function." Ex. 12 at 3 – 4. And the therapist recorded that Petitioner had achieved her short-term goals of independence in her HEP and full ROM, but not her long-term goals of 90% normal function and symmetrical scapular motion. *Id.* The therapist recommended ongoing PT 2 – 3 times per week for 4 weeks. *Id.* However, no further records have been filed.

Petitioner's witness statement maintains that during the seven-month gap in medical record documentation, she had residual shoulder symptoms despite diligent adherence to her HEP. Ex. 1 at ¶ 13. Around this time, her husband and stepson were diagnosed with COVID-19, and she decided to limit in-person contact with others to what was "absolutely necessary." *Id.* She ultimately obtained the PT reevaluation to determine whether she needed to revise her HEP; no changes were recommended, but she attests that her symptoms have persisted. *Id.*

I have also reviewed a June 2023 email from Petitioner's counsel, and a response from Petitioner's physical therapist. *See generally* Ex. 16.

IV. Analysis

After a review of the entire record, I find that preponderant evidence supports Petitioner's entitlement for a Table SIRVA.

The first issue to be resolved is whether Petitioner has demonstrated residual effects of the alleged left shoulder injury for more than six months after the September 22, 2020, vaccination. Section 11(c)(1)(D)(i). This is a threshold requirement for pursuing compensation under the Program for any class of claim. *Black v. Sec'y of Health & Hum. Servs.*, 33 Fed. Cl. 546, 550 (1995) (reasoning that the "potential petitioner" must not only make a *prima facie* case, but clear a jurisdictional threshold, by "submitting supporting documentation which reasonably demonstrates that a special master has jurisdiction to hear the merits of the case"), *aff'd*, 93 F.3d 781 (Fed. Cir. 1996) (internal citations omitted).

Respondent argues that severity cannot be established, emphasizing the gap in medical record documentation between November 19, 2020, and the one additional PT encounter on June 15, 2021. Rule 4(c) Report at 4. And Respondent contends that this PT record does not sufficiently document an ongoing shoulder injury (given the very similar exam findings when compared to the PT initial evaluation) or any new treatment plan, and in Respondent's view, the additional PT record was solely generated to help support Petitioner's compensation claim. *Id.* at 4 – 5, n. 3.

However, Respondent gives insufficient weight to Petitioner's receipt of a steroid injection, and the PT records indicating an ongoing injury, just before the treatment gap. The PT records also emphasize that Petitioner was instructed to rely on an independent home exercise program ("HEP"). And this is not a case with intervening medical encounters for any unrelated concerns, or any positive evidence indicating that her shoulder had fully recovered, or that some intervening new injury had occurred. Moreover, while a treatment gap of seven months is somewhat lengthy, it is not inconsistent with the mild injury that was documented upon Petitioner's return to PT on June 15, 2021.

The PT records are clearly imperfect, starting with their initial mis-documentation of abnormal physical exam findings as being in Petitioner's right, rather than left, arm. Moreover, the identical physical exam findings suggest that *some* information was carried over from the record of the November 2020 PT initial evaluation to the June 2021 PT re-evaluation.[11] Nonetheless in June 2021, the therapist assessed an ongoing shoulder injury (specifically including a disability rating of 16/100, less than 90% function, and asymmetric scapular function). Taken together, the medical records contain preponderant evidence of injury persisting at a mild level until nine months after vaccination.

Respondent also briefly suggests that the Table onset requirement, at 42 C.F.R. §§ 100.3(a) and (c)(10)(ii), is not met. Rule 4(c) Report at 6. But as noted above (and in Petitioner's Motion at 13 – 14 (preceding the Rule 4(c) Report), the medical records starting just 20 days post-vaccination (plus the even earlier text messages with medical providers) reflect Petitioner's consistent history of shoulder pain as beginning with the vaccination and persisting over time. Moreover, there is no evidence to suggest a different onset. There is preponderant evidence of shoulder pain onset occurring within 48 hours of vaccination.[12]

Conclusion and Scheduling Order

Respondent does not raise any other objections to entitlement (*see generally* Rule 4(c) Report), and based on my independent review, I find that Petitioner has preponderantly established all other requirements for a Table SIRVA claim. 42 C.F.R. §§

[11] The June 2023 emails between Petitioner's counsel and her physical therapist (Ex. 16) are not particularly persuasive. As Respondent persuasively notes (Response at 1 – 2), the therapist responded about his recordkeeping practices generally, rather than offering specific recollections of his reevaluation of Petitioner roughly two years after the fact.

[12] Respondent also suggests that Petitioner must establish the onset of *reduced range of motion* within 48 hours of vaccine administration. Rule 4(c) Report at 6. But 42 C.F.R. § 100.3(c)(10)(ii) makes no reference to range of motion occurring within a specified time-frame as a SIRVA requirement, and that provision has been interpreted to require *only* proof of pain in the 48-hour period post-vaccination.

100.3(a), (c)(10)(i, iii, and iv). Accordingly, she need not prove causation-in-fact. Section 11(c)(1)(C). I also find that Petitioner has satisfied all other requirements of Section 11(c) including the lack of other award or settlement. Sections 11(c)(A), (B), and (D).

For the foregoing reasons, **I find that Petitioner has established entitlement and is thus entitled to compensation for a left-sided SIRVA following administration of the flu vaccine on September 22, 2020.**

The case is now formally in the damages phase. But as detailed above, notwithstanding the rather prompt medical evaluations, the injury did not involve high pain ratings or severely reduced range of motion. Following a brief course of oral steroids and one steroid injection, the injury was manageable with a home exercise program. It was last documented just nine months post-vaccination. Petitioner's request for $55,000.00 for her pain and suffering (plus some out-of-pocket expenses), *see* Motion at 23 – 25, is not obviously unreasonable. The parties are encouraged to pursue informal resolution of an appropriate damages award, even if it involves some compromise on both sides.[13]

If the parties determine that informal resolution is not possible, they should be prepared to promptly complete their damages briefing (i.e., a response from Respondent, followed by any brief reply from Petitioner). Afterwards, subject to my availability and overall docket considerations, the case may potentially be scheduled for an expedited damages hearing, which would then be memorialized in a "short-form" decision that fully incorporates and relies upon the hearing transcript.

By no later than Friday, October 18, 2024, Petitioner shall file a Status Report updating on the parties' efforts towards informally resolving damages – specifically stating the date on which Respondent responded to Petitioner's damages position, *see* Brief at 23 - 25. If Respondent has not yet responded, the parties shall confer, and Petitioner shall report the date by which Respondent expects to respond.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[13] Moreover, while I recognize Petitioner and her counsel's frustration with the delayed medical review of the claim in 2022-23, it might have been more productive for Petitioner to convey a demand, rather than opting for a motion for a ruling on the record – which only led to further briefing from both sides (and increasingly combative language from Petitioner).